WE CLAIM:

1. The compound 4-amino-l-hydroxybutylidene-1,1-bisphosphonic acid monosodium salt having water content of 1.3 % to 11.7%.
2. A hydrate form of a compound of claim 1 which is any of the hydrate forms selected from the group that consists of 1/4 hydrate, 1/3 hydrate, hemihydrate, 2/3 hydrate, 3/4 hydrate, monohydrate, 5/4 hydrate, 4/3 hydrate, 3/2 hydrate, and dehydrate.
3. The compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid monosodium salt having water content of 5.1 % to 7.0%.
4. The compound according to claim 3 having water content of about 6.2%.
5. Alendronate monosodium monohydrate.
6. The compound according to claim 3, which is characterized by peaks in the powder xray diffraction at values of two theta of 12.7 ±0.2, 16.2 ±0.2, 17.3 ±0.2, 17.6 ±0.2, 24.8 ±0.2, and 25.5 ±0.2.
7. A method of preparing the compound of any of claims 3 through 6 comprising the steps of:
   a) reacting one equivalent of 4-amino-l-hydroxybutylidene-1,1-bisphosphonic acid with one equivalent of sodium base in a lower alkanol comprising 5 to 200 equivalents of water; and
   b) isolating said compound of any of claims 3 through 6.
8. A method according to claim 7 wherein the compound 4-amino-l-hydroxybutylidene- 1, 1 -bisphosphonic acid is in a monohydrate form.
9. A method according to claim 7 wherein the lower alkanol is selected from the group consisting of methanol, ethanol and isopropanol.
10. A method according to claim 7 wherein the sodium base is selected from the group consisting of sodium hydroxide, sodium methoxide and sodium ethoxide.
11. A method according to claim 7 wherein the compound 4-amino-1-hydroxybutylidene-

1, 1-bisphosphonic acid is in an anhydrous form.

12. A method of preparing the compound of any of claims 3 through 6 comprising the steps of:

a) treating 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic monosodium salt in a lower alkanol with 20-40 equivalents of water; and

b) isolating said compound of any of claims 3 through 6.

13. A method according to claim 12 wherein the lower alkanol of step a) is ethanol.

14. A method of preparing the compound of any of claims 3 through 6 comprising the steps of:

a) treating 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic disodium salt in a lower alkanol with 20-40 equivalents of water, and one equivalent of alendronic acid; and

b) isolating said compound of any of claims 3 through 6.

15. A method according to claim 14 wherein the lower alkanol of step a) is ethanol.

16. A method of preparing the compound of any of claims 3 through 6 comprising the steps of:

a) treating 4-amino-1-hydroxybutylidene-1,1-bisphosphonic trisodium salt in a lower alkanol with 20-40 equivalents of water and two equivalents of alendronic acid; and

b) isolating said compound of any of claims 3 through 6.

17. A method according to claim 16 wherein the lower alkanol of step a) is ethanol.

18. A method of preparing the compound of any of claims 3 through 6 comprising the steps of:

a) treating 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic tetrasodium salt in a lower alkanol with 20-40 equivalents of water and three equivalents of alendronic acid; and

b) isolating said compound of any of claims 3 through 6.

19. A method according to claim 18 wherein the lower alkanol of step a) is ethanol.

20. A method according to claim 12 in which the 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic sodium salt is a monosodium salt trihydrate.

21. A compound according to claim 3, which is characterized by peaks in the powder x-ray diffraction at values of two theta of 9.3 ±0.2, 12.4 ±0.2, 13.5 ±0.2, 26.3 ±0.2 and 30.0 ±0.2.

22. A method of preparing the compound of claim 21 comprising the steps of:

a) treating 4-amino-1-hydroxybutylidene-1,1-bisphosphonic monosodium trihydrate with an effective amount of a drying agent; and

b) isolating said compound of claim 21.

23. A method according to claim 22 wherein the reaction of step a) is performed in ethanol.

24. Alendronate monosodium hemihydrate.

25. The compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid monosodium salt having water content of 2.8% to 3.9%.

26. The compound according to claim 25 having water content of about 3.2%.

27. The compound according to claim 25, which is characterized by peaks in the powder x-ray diffraction at values of two theta of 7.0 ±0.2, 9.3 ±0.2, and 14.0 ±0.2.

28. A method of preparing the compound of claim 24 or 25 comprising the steps of:

a) treating 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid in a lower alkanol with one equivalent of sodium base and 9 to 15 equivalents of water; and

b) isolating said compound of claim 24 or 25.

29. A method according to claim 28 wherein the compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid is in a monohydrate form.

30. A method according to claim 28 wherein the lower alkanol is selected from the group consisting of methanol, ethanol and isopropanol.

31. A method according to claim 28 wherein the sodium base is selected from the group consisting of sodium hydroxide, sodium methoxide and sodium ethoxide.

32. A method according to claim 28 wherein the compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid is in an anhydrous form.

33. The compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid monosodium salt having water content of 2.5% to 3.5%.

34. The compound according to claim 33, which is characterized by peaks in the powder x-ray diffraction at values of two theta of 9.2 ±0.2, 14.2 ±0.2, 15.0 ±0.2, 17.1 ±0.2, 20.7 ±0.2, 22.0 ±0.2, 22.4 ±0.2.

35. A method of preparing the compound of claim 2 or 33 comprising the steps of:

a) treating 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid in a lower alkanol with one equivalent of sodium base and 17 to 22 equivalents of water; and

b) isolating said compound of claim 2 or 33.

36. A method according to claim 35 in which the compound 4-amino-1 - hydroxybutylidene-1, 1-bisphosphonic acid is in a monohydrate form.

37. A method according to claim 35 wherein the lower alkanol is selected from the group consisting of methanol, ethanol and isopropanol.

38. A method according to claim 35 wherein the sodium base is selected from the group consisting of sodium hydroxide, sodium methoxide and sodium ethoxide.

39. The compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid monosodium salt having water content of 6.4% to 9.0%.

40. The compound according to claim 39, which is characterized by peaks in the powder x-ray diffraction at values of two theta of 12.2 ±0.2, 13.3 ±0.2, 14.8 ±0.2, 15.8 ±0.2, 16.3 ±0.2, and 17.2 ±0.2.

41. A method of preparing the compound of claim 2 or 39 comprising the steps of:

a) treating 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid in a lower alkanol with one equivalent of sodium base and 0 to 4 equivalents of water; and

b) isolating said compound of claim 2 or 39.

42. A method according to claim 41 in which the compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid is in a monohydrate form.

43. A method according to claim 41 wherein the lower alkanol is selected from the group consisting of methanol, ethanol and isopropanol.

44. A method according to claim 41 wherein the sodium base is selected from the group consisting of sodium hydroxide, sodium methoxide and sodium ethoxide.

45. The compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid monosodium salt having water content of 3.2% to 5.8%.

46. The compound according to claim 45, which is characterized by peaks in the powder x-ray diffraction at values of two theta of 13.1 ±0.2, 15.2 ±0.2, 16.3 ±0.2, 22.3 ±0.2, 22.5 ±0.2, 23.4 ±0.2, and 23.7 ±0.2.

47. A method of preparing the compound of 2 or 45 comprising the steps of:

a) treating 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid anhydrous in a lower alkanol with one equivalent of sodium base and 0 to 4 equivalents of water; and

b) isolating said compound of claim 2 or 45.

48. A method according to claim 47 in which the compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid is in an anhydrous form.

49. A method according to claim 48 wherein the lower alkanol is selected from the group consisting of methanol, ethanol and isopropanol.

50. A method according to claim 48 wherein the sodium base is selected from the group consisting of sodium hydroxide, sodium methoxide and sodium ethoxide.

51. The compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid monosodium salt

having water content of 1.3 % to 3.1 %.

52. The compound according to claim 51, which is characterized by peaks in the powder x-ray diffraction at values of two theta of 13.0 ±0.2, 13.4 ±0.2, 14.2 ±0.2, 19.1±0.2, and 19.4 ±0.2.

53. A method of preparing the compound of claim 2 or 51 comprising the steps of:

a) treating 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid in a lower alkanol with one equivalent of sodium base and 3 to 20 equivalents of water; and

b) isolating said compound of claim 2 or 51.

54. A method according to claim 53 in which the compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid is in a monohydrate form.

55. A method according to claim 53 wherein the lower alkanol is selected from the group consisting of methanol, ethanol and isopropanol.

56. A method according to claim 53 wherein the sodium base is selected from the group consisting of sodium hydroxide, sodium methoxide and sodium ethoxide.

57. A method according to claim 53 wherein the compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid is in an anhydrous form.

58. Alendronate monosodium dihydrate.

59. The compound 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid monosodium salt having water content of about 11.7%.

60. The compound according to claim 59, which is characterized by peaks in the powder x-ray diffraction at values of two theta of 9.3 ±0.2, 12.4 ±0.2, 13.5 ±0.2, 26.3 ±0.2 and 30.0 ±0.2.

61. A method for preparing a compound according to claim 58 or 59 comprising the steps of:

a) treating 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid monosodium salt trihydrate with an effective amount of drying agent; and

b) isolating 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid the monosodium salt dihydrate.

62. A pharmaceutical composition comprising a pharmaceutically effective amount of a compound of any of claims 1, 3, 25, 33, 39, 45 and 51.

63. A method for treating and/or preventing bone loss in a subject, comprising the step of administering to said subject in need thereof an effective amount of the pharmaceutical composition as defined in claim 62.

64. A method of preparing the compound of claim 1 comprising the steps of:

a) reacting one equivalent of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid with one equivalent of sodium base in an aqueous organic solvent selected from the group consisting of acetone, DMSO, DMF, acetonitrile, alcohols, polyalcohols, polyalcohol ethers, pyridine, sulfolane, N-methyl pyrrolidinone and dioxane, and

b) isolating said compound of claim 1.

65. A method of preparing the compound of claim 3 comprising the steps of:

a) reacting one equivalent of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid with one equivalent of sodium base in an aqueous organic solvent selected from the group consisting of acetone, DMSO, DMF, acetonitrile, alcohols, polyalcohols, polyalcohol ethers, pyridine, sulfolane, N-methyl pyrrolidinone and dioxane, and

b) isolating said compound of claim 3.

66. A method of preparing the compound of claim 25 comprising the steps of:

a) reacting one equivalent of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid with one equivalent of sodium base in an aqueous organic solvent selected from the group consisting of acetone, DMSO, DMF, acetonitrile, alcohols, polyalcohols, polyalcohol ethers, pyridine, sulfolane, N-methyl pyrrolidinone

and dioxane, and

b) isolating said compound of claim 25.

67. A method of preparing the compound of claim 33 comprising the steps of:

a) reacting one equivalent of 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid with one equivalent of sodium base in an aqueous organic solvent selected from the group consisting of acetone, DMSO, DMF, acetonitrile, alcohols, polyalcohols, polyalcohol ethers, pyridine, sulfolane, N-methyl pyrrolidinone and dioxane, and

b) isolating said compound of claim 33.

68. A method of preparing the compound of claim 39 comprising the steps of:

a) reacting one equivalent of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid with one equivalent of sodium base in an aqueous organic solvent selected from the group consisting of acetone, DMSO, DMF, acetonitrile, alcohols, polyalcohols, polyalcohol ethers, pyridine, sulfolane, N-methyl pyrrolidinone and dioxane, and

b) isolating said compound of claim 39.

69. A method of preparing the compound of claim 45 comprising the steps of:

a) reacting one equivalent of 4-amino- 1-hydroxybutylidene-1, 1-bisphosphonic acid with one equivalent of sodium base in an aqueous organic solvent selected from the group consisting of acetone, DMSO, DMF, acetonitrile, alcohols, polyalcohols, polyalcohol ethers, pyridine, sulfolane, N-methyl pyrrolidinone and dioxane, and

b) isolating said compound of claim 45.

70. A method of preparing the compound of claim 51 comprising the steps of:

a) reacting one equivalent of 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid with one equivalent of sodium base in an aqueous organic solvent selected

from the group consisting of acetone, DMSO, DMF, acetonitrile, alcohols, polyalcohols, polyalcohol ethers, pyridine, sulfolane, N-methyl pyrrolidinone and dioxane, and

b) isolating said compound of claim 51.

71. A method of preparing the compound of claim 59 comprising the steps of:

a) reacting one equivalent of 4-amino-l-hydroxybutylidene-1, 1-bisphosphonic acid with one equivalent of sodium base in an aqueous organic solvent selected from the group consisting of. acetone, DMSO, DMF, acetonitrile, alcohols, polyalcohols, polyalcohol ethers, pyridine, sulfolane, N-methyl pyrrolidinone and dioxane, and

b) isolating said compound of claim 59.